

Rejections under 35 U.S.C. § 112(1).

The Examiner maintains his rejection of Claims 24-33, 35, 36, 38, 41, 42 and 44-46 under Section 112(1) for lack of enablement. This rejection is respectfully traversed.

The Examiner acknowledges the specification is enabling for increasing and/or decreasing blood flow to the vagina by inhaling particular commercial odorants or mixtures thereof.

The Examiner denies the enablement of Applicant's inventive article of manufacture based on an "unusual disclosed functional effect" and an "unusual use" and characterizes the disclosed odorants/odorant mixtures as being "*undefined*." The Examiner requires that the claims be limited to the particular listed commercial odorants or mixtures.

The Examiner maintains that the instantly claimed odorants are highly subjective with respect to the actual odors being encompassed, giving a recipe of pumpkin pie or banana nut bread -which can vary according to the ingredients - as evidence that the odors emitted would be speculative based on a particular recipe.

The Examiner points to Doty (Philadelphia Sensorics, 1983) at pages 16-18, as disclosing "numerous variables such as an individual's occupation, general health, psychological state, and age which play a role in assessing sensory function of smell," and then concluding that altering blood flow to the vagina using odorants other than the particular commercially identified odorants would be highly unpredictable between females based on such variables.

Doty (Philadelphia Sensorics, 1983) discloses a Smell Identification Test™ involving 50 microencapsulated odorants for release of odorants for inhalation. The test subject is required to inhale each odorant, and to attempt to *identify* each odorant from a series of choices.

Doty describes (at page 3) conducting five initial experiments to develop the Smell Identification Test™: Exp. 1: selection of stimuli; Exp. 2: *examination of influence of variables such as the age, gender, and ethnic background of subjects on the scores of the developed Smell Identification Test™*; Exp. 3: use of the test to discriminate among person with olfactory disorders; Exp. 4: determining test-retest reliability; and Exp. 5: comparison of test scores to results from a traditional detection threshold procedure.

Referring to Experiment 2 (pages 5-9), the study involved identification of 50 stimulants in a forced-choice set-up where alternative responses were provided. In a second phase of

Exp. 2, a series of multiple regression analyses were performed on the data to determine what influences a number of demographic variables had on the *stimulant identification* test scores, namely, age, gender, race and smoking habits.

At the cited pages 16-18, Doty is describing interpretation of the results of the Smell Identification Test™ within the context of the individual's occupation, general health, and psychological state. Doty further discloses that an individual's age and gender were also taken into consideration when evaluating the test results of the Smell Identification Test™, which results related to the diminishment of an individual's ability to smell over time. Doty provides norms (normal test scores) based on the results of the stimulant identification study for male and female age groups (Tables 1 and 2), that relate to olfactory ability, that is anosmic (total inability to perceive qualitative odor sensations), microsmic (decreased smell ability), or normosmic ability to smell a substance.

Doty provides information related to *an odor identification* test, and factors that can influence *identification* of odor stimulants. There is nothing in Doty that relates to odorants for altering blood flow to the vagina of a female individual.

Doty provides no basis for the Examiner's conclusion that the use of odorant sources other than the particular commercially identified odorants for altering blood flow to the vagina within the context of Applicant's claimed invention, would be highly unpredictable between females. The Examiner's statements regarding Doty are clearly unsupported.

The Examiner also concludes that altering blood flow to the vagina using odorants other than the particular commercially identified odorants would be highly unpredictable between females on the basis that using the same mixture of odorants can cause an increased blood flow to the vagina in some females and a decreased blood flow to the vagina in other females. The Examiner further concludes that it would take undue experimentation to prepare and use an article of manufacture as claimed with other than the particular demonstrated commercial odorant mixtures to provide the claimed alteration in blood flow to the vagina.

Applicant has disclosed that odorants can be screened for effectiveness in increasing or decreasing blood flow to the vagina and measured either subjectively through interviewing the female subject, or objectively by administering a physical test to measure levels of blood flow to

the vagina before and after being given the odorant mixture and comparing the results. See, specification at pages 6-7. As described in the Example at page 9, a photophlethysmograph (vaginal process graphic recording device) can be utilized to monitor change in blood flow to the vagina.

Applicant has additionally taught that the variation in altering blood flow by certain odorant mixture(s) referred to by the Examiner was based upon particular preferences for certain defined sexual activities. The Examiner is directed to the Example at page 13, line 13 to page 16, line 5. Thus, the Examiner's statements as to the unpredictability of using other than the identified commercial forms of the odorants is without basis. Clearly, one of ordinary skill in the odorant arts would be fully enabled to practice Applicant's invention as claimed utilizing odorant mixtures – both synthetic and natural – as broadly as presently claimed.

It is respectfully submitted that Applicant's disclosure is fully enabling for odorants other than the particular commercial sources provided by Applicant. According to Section 112, an Applicant is required to teach how to use an invention, and it is well settled that it is not necessary that the specification disclose every operative example when one skilled in the art is fully apprised by the disclosure of what the invention is and how to use it. A disclosure that contains representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of the claim will possess the described utility is all that is required. It is respectfully submitted that the nature of the recited odorants is not ambiguous to one skilled in the odorants arts and would be readily ascertainable.

Applicant has provided sources of commercial odorants, which are exemplary, from which one skilled in the odorant arts would be able to readily identify suitable odorants from other sources - both synthetic (commercially prepared) and natural sources (e.g., essential oils) - that have the recited odorant characteristic to formulate the recited odorant mixture that would achieve the desired effect to alter blood flow to the vagina when inhaled by a female individual. As recited in the claims, suitable odorant mixtures are those having the recited characteristic of a mixture of: a) a licorice-based odorant and banana nut bread odorant, b) a licorice-based odorant and a cucumber odorant, c) a lavender odorant and a pumpkin pie odorant, and d) a baby powder odorant and a chocolate odorant.

It is well known in the art to utilize such methods as gas chromatography -mass spectrometry (GC-MS). among others, to determine the aroma components of an odorant compound. A gas chromatograph distinguishes compounds by comparing to a reference standard. The Examiner is respectfully directed to the following enclosed examples of Abstracts that address the identification of aroma components that contribute to various odorants: Jordan et al., "Aromatic profile of aqueous banana essence and banana fruit by gas chromatography-mass spectrometry (GC-MS) and gas chromatography-olfactometry (GC-O)," *J. Agric. Food Chem.* 49(10):4813-7 (2001); Zhou et al., "Identification and quantification of aroma-active components that contribute to the distinct malty flavor of buckwheat honey," *J. Agric. Food Chem.* 50(7): 2016-21 (2002). See also, Hamilton et al., "Measuring Farmstead Odors," Oklahoma Cooperative Extension Service, OSU Extension Facts F-1740 (06-1999), at (<http://agweb.okstate.edu/pearl/biosystems/general/fl740.htm>) which discusses the use of a gas chromatograph with a mass spectrometer detector in odorant analysis. See also, *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc. (1985) at page 844, which discusses the use of instrumental techniques to separate and identify volatile organic substances, for example, capillary gas chromatography columns in tandem with a mass spectrometer, Fourier transform nmr spectroscopy.

Those of ordinary skill in the art of odor science would readily utilize such known and used instruments as a gas chromatograph with a mass spectrometer detector to identify and/or prepare an odorant such as a licorice-based odorant, banana nut bread odorant, and so forth, according to an established quality - which in the present application can be ascertained by utilizing the described commercial source odorants as a comparative standard, for example.

The characteristics of the odorants in the mixtures recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily ascertain and provide suitable odorant mixtures from various sources that have the recited odorant character (e.g., mixture of licorice-based and cucumber odorants, etc.) and that would achieve the desired effect of altering blood flow to the vagina when inhaled by a female individual according to Applicant's invention.

It is further pointed out that natural sources of the odorants can be utilized in Applicant's method. As disclosed in the specification at page 4, lines 16-19, odorants can be utilized from

commercial sources and as essential oils (i.e., volatile material isolated from a plant source), for example. See, enclosed pages 810-811 from *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc. (1985) discussing essential oils. For example, a natural source of lavender are flowers of *Lavandula spica* (*Ilavandula officinalis* or *Lavandula vera*) which contains a volatile oil with the principal constituent *l*-linalyl acetate. A natural source of licorice can be derived the dried rhizome and roots of *Glycyrrhiza glabra* L., *G. glabra* L. var. *glandulifera*, or other varieties. See, *The Merck Index*, 11th Ed., Entry 5261 (lavender) and Entry 4400 (glycyrrhiza), Merck & Co., Inc. (1989); *Remington's Pharmaceutical Sciences*, 18th Ed., Mack Publishing Co., Easton, Pennsylvania (1990) at pages 1294 and 1300. Natural sources of odorants are well known in the art.

Furthermore, satisfaction of the enablement requirement of Section 112 is not precluded by the necessity for some experimentation, such as routine screening. The key word is "undue" not "experimentation." *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Jackson*, 217 USPA 804 (Bd. App. 1982).

Applicant has provided a specific working example and described an embodiment of his invention and the manner for ascertaining effectiveness to teach those of ordinary skill in the art how to make and use the invention as broadly as it is claimed, and to show that the claimed odorant mixtures are useful in altering blood flow to the vagina of a female subject. Therefore, odorants other than the particular commercial odorants disclosed by Applicant could be utilized to practice the claimed invention without undue experimentation.

Applicant respectfully submits that the Examiner has not complied with his duty to provide a basis to support his contention that the specification is not enabling as to the present claims, which are sufficiently supported by the specification. The present disclosure of commercial sources of those odorants and a working example is more than adequate to enable one of ordinary skill in this art area to carry out the invention commensurate with the scope of claims, as required under Section 112(1) to utilize odorants – both synthetic and natural – other than the particular commercial odorants exemplified. To require Applicant to limit his claims to those odorants that are expressly exemplified is contrary to the purpose of the Patent Laws.

Based on Applicant's disclosure and the understanding in the art, it is submitted that the requirements under Section 112(1) have clearly been met in the present disclosure, and that an art worker in this area is fully enabled to practice Applicant's invention as broadly as it is claimed.

Accordingly, it is respectfully submitted that the claims fully comply with Section 112(1), and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §112(2).

The Examiner also maintains the rejection of Claims 24-33, 35, 36, 38, 41, 42 and 44-46 under Section 112(2) for the use of indefinite claim language.

The Examiner contends that the metes and bounds of the odorants recited in the claims are not adequately delineated. The Examiner contends that the "subjective nature of the recited odorants (any of which is deemed essential in terms of adequately defining these particular active ingredients in the claimed article of manufacture) causes these claims to be very ambiguous and unclear." The Examiner maintains that the instantly claimed odorants are highly subjective with respect to the actual odors being encompassed, giving a recipe of pumpkin pie or banana nut bread -which can vary according to the ingredients - as evidence that the odors emitted would be speculative based on a particular recipe. The Examiner further contends that the odorants instantly disclosed and claimed have unusual functional effects, and thus should be limited to the disclosed commercial sources.

Applicant's claims are directed to articles of manufacture comprising the following odorant mixtures: a) a licorice-based odorant and banana nut bread odorant, b) a licorice-based odorant and a cucumber odorant, c) a lavender odorant and a pumpkin pie odorant, and d) a baby powder odorant and a chocolate odorant. The identity and character of the odorants that comprise the recited mixtures are well understood and clear in their meaning by one of ordinary skill in the odorant arts. One skilled in the odorant arts would be able to readily identify suitable odorants from various sources – both synthetic and natural – that have the recited odorant character for the particular odorant mixture to achieve the desired effect.

The terms licorice, cucumber, lavender, pumpkin pie, baby powder, and chocolate odorants have been utilized in various contexts including Applicant's own issued patents as well

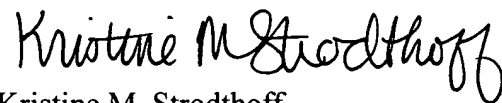
as other issued patents and publications — *including the cited Doty publication* (see page 7 listing licorice, chocolate, pumpkin pie odorants), for example. The Examiner is also directed to the claims Applicant's issued patents as evidence that the terms satisfy the requirements of Section 112(2), which merely requires that the claims set out and circumscribe a particular area that the Applicant regards as the invention with a reasonable degree of particularity: USP 5,885,614 (licorice odorant, pumpkin pie odorant, baby powder odorant, chocolate odorant), USP 5,759,521 (cucumber odorant), USP 6,106,837 (chocolate odorant, lavender odorant), and USP 5,904,916 (lavender odorant).

One skilled in the odorant arts would understand the metes and bounds of those terms in the claims when read in light of the specification, which sets forth examples for such odorants, and in view of the knowledge in the art, as evidenced by Applicant's issued patents and Doty's publication, among others. It is respectfully submitted that the nature and identity of the recited odorants is not ambiguous to one skilled in the odorants arts.

Based on that information, and the reasons stated above, it is respectfully submitted that, based on the present disclosure, is well within the understanding in the art to identify appropriate odorants for use in Applicant's invention. Accordingly, it is submitted that the claims are clear in their meaning and satisfy the requirements of Section 112(2), and withdrawal of this rejection is respectfully requested.

Based on the amendments and above remarks, it is submitted that the present claims are in condition for allowance, and notification to that effect is respectfully requested.

Respectfully submitted,



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Enclosures: Cited references